New York operate differently, with their own agencies that regulate laboratory testing, including certification and inspection programs.

The CLIA program is 100% user-fee financed and jointly administered by three agencies within the Department of Health and Human Services—FDA, CMS, and the Centers for Disease Control and Prevention (CDC). Each agency has a unique role in assuring quality laboratory testing (Table 1). CLIA compliance is essential for getting reimbursement from federally funded programs such as Medicare and Medicaid and other insurance agencies.

Laboratories can obtain multiple types of CLIA certificates based on the kinds of testing they perform, including point-of-care testing (POCT), provider-performed microscopy (PPM), moderate complexity, and high complexity. Under CLIA regulations, when a laboratory uses a test system that has

<table>
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<th>CLIA Administration</th>
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<td><strong>Federal Agency</strong></td>
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<td>CMS</td>
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CMS, Centers for Medicare and Medicaid Services; FDA, Food and Drug Administration; CDC, Centers for Disease Control and Prevention; PT, proficiency testing


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**NEXT GENERATION ASSAYS**

**THERAPEUTIC DRUG MONITORING ASSAYS & URINE DRUG TESTS**

- ARK introduces its homogeneous enzyme immunoassay technology for the next generation of clinical laboratory testing.
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- ARK produces assays of high-quality that yield rapid and reliable results on automated clinical chemistry analyzers.

**EPILEPSY**
- Levetiracetam
- Lamotrigine
- Gabapentin
- Topiramate
- Zonisamide
- Oxcarbazepine Metabolite
  - CE Mark, Not FDA Cleared
- Lacosamide
  - CE Mark, Not FDA Cleared

**URINE DRUG TESTS**
- Pregabalin
  - CE Mark, Forensic Use Only
- Fentanyl
  - CE Mark, Not FDA Cleared
  - In Development
- ESG
- Tramadol
- Meperidine
- Ketamine
- Methylphenidate Metabolite

**CANCER**
- Methotrexate
- Efavirenz
- Lopinavir
- Nevirapine

**ANTIRETROVIRAL**
- CE Mark, FDA de novo granted
- In Development
- Voriconazole II

**ANTIBIOTIC**
- Linezolid
- In Development

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